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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,776

11/13/2003

Richard S. Sanders

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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

P.O. BOX 2938

MINNEAPOLIS, MN 55402

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

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3762

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DELIVERY MODE

03/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,776	Applicant(s) SANDERS, RICHARD S.	
	Examiner MICHAEL KAHRELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 57-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 57-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/13/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-10 and 57-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine (US 6,477,417, hereinafter "Levine") in view of Branham et al. (US 5,687,737, hereinafter "Branham") and Morgan (US 5,024,221, hereinafter "Morgan").

4. In regards to claim 1-5, Levine discloses a sensing circuit (82, 84 and 108), a pacing circuit (70 and 78), and a processor that is upgradeable from a cardiac monitor controller to a cardiac pacemaker controller wherein the sensing circuit is adapted to be programmed from a far-field sensing configuration to an intracardiac electrogram

Art Unit: 3762

sensing configuration (col. 2, line 2). The Examiner is interpreting this as an “upgrade” because it provides improved performance inasmuch as sensing and stimulating a local area of the heart. Further, the pacing circuit is adapted to be inactive when the device is configured to be the cardiac monitor and the pacemaker (col. 2, line 9), and the device is capable of producing pacing pulses when the device is configured to be the monitor or pacemaker. Since “triggered mode” is used by Levine’s device, the pacing circuit is inactive between pulses (e.g., the disclosed “time-out” period) in either the monitor (far-field sensing) mode or pacemaker (near-field sensing) mode, but is also still capable of delivering pulses in either mode (e.g., after the “time-out” interval). Levine does not expressly disclose programming the sensing circuit to have a first set of cutoff frequencies for far-field sensing while the pacing circuit is inactive and a second set of cutoff frequencies for near-field sensing when the pacing circuit is active using the claimed frequencies. Branham teaches using a first and second bandpass filter cutoff frequency based on whether unipolar or bipolar electrodes to provide the predictable result of filtering noise specific to a particular electrode configuration, and Morgan teaches providing a cardiac stimulator with a programmable band-pass filter (i.e. a first and second filter) to fit the frequency characteristics to the particular implantation (abstract). Further, it is well known in the art to provide the different claimed cutoff frequencies for near-field and far-field sensing to provide the predictable result of acquiring the desired heart signal, while excluding noise based on the electrode configuration. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Levine’s device by providing a cardiac

Art Unit: 3762

stimulator with a programmable band-pass filter with different cutoff frequencies for the unipolar and bipolar modes to provide the predictable result of fitting the frequency characteristics to the particular implantation and electrode configuration, and the claimed cutoff frequencies for near-field and far-field sensing to provide the predictable result of acquiring the desired heart signal, while excluding noise based on the electrode configuration.

5. In regards to claim 6, the device comprises RAM containing control code (col. 9, line 54).

6. In regards to claim 7, the device comprises an activity sensor (col. 14, line 35).

7. In regards to claim 8, an electrogram is stored (col. 13, line 45).

8. In regards to claims 9 and 10, the device further comprises an activity detector comprising an arrhythmia detector (col. 13, lines 21-40).

9. In regards to claim 61, the configuration instructions are received via telemetry (col. 2, line 2).

10. In regards to claim 65, the sensing circuit is adapted to sense an activity signal (col. 14, line 20).

11. In regards to claim 66, the device comprises a cardiac resynchronization device (118).

12. In regards to claims 57-60 and 62-64, Levine discloses the essential features of the claimed invention including upgrading the device(s) via programming, but does not disclose a memory comprising a ROM portion and updatable/re-allocatable RAM portion, a safety operation mode during upgrading, configuration instructions comprising

Art Unit: 3762

authorization information specific to the device being configured, or a configuration authorization module that generates a permission signal upon verification of authorization information. It is well known in the art to provide implantable cardiac stimulators with a memory comprising a ROM portion and updatable/re-allocatable RAM portion to provide a memory that is resistant to corruption and still modifiable for adapting to the heart's changing conditions; a safety (or fallback) operation mode during telemetry to prevent life-threatening arrhythmia when the processor is busy with communication functions; and a handshake protocol specific to the device being configured to ensure that the instructions being telemetered to a device are appropriate for the specific device implanted in the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Levine's device with a memory comprising a ROM portion and updatable/re-allocatable RAM portion to provide the predictable results of providing a memory that is resistant to corruption and still modifiable for adapting to the heart's changing conditions; a safety (or fallback) operation mode during telemetry to provide the predictable result of preventing life-threatening arrhythmia when the processor is busy with communication functions; and a handshake protocol specific to the device being configured to provide the predictable result of ensuring that the instructions being telemetered to a device are appropriate for the specific device implanted in the patient.

Response to Arguments

13. Applicant's arguments filed 1/13/2009 have been fully considered but they are not persuasive. Applicant argued that the cited references fail to disclose cutoff

Art Unit: 3762

frequencies programmed to a first set of values while the pacing circuit is inactive and programmed to a second set of values suitable for intracardiac electrogram sensing.

However, Levine is applied for a teaching of a device which is programmable to operate in either a far-field (unipolar) sensing mode or an intracardiac (bipolar) sensing mode.

Branham and Morgan are relied upon for the teaching that it is known to use different high and low cutoffs for a bandpass filter based on whether the signal sensed is far-field or intracardiac. Levine's pacing circuit is adapted to be both inactive and capable of producing pulses in either and both modes (as elaborated above, referring to the "triggered mode"). In other words, the prior art (as modified by Branham and Morgan) is adapted to have both the first *and* second sets of bandpass filter values while the pacing circuit is inactive (depending on whether the unipolar or bipolar mode is being used), and have the first and second sets of values for the filter when the circuit is capable of producing pacing pulses (also depending on whether the unipolar or bipolar mode is being used). The claim language requires only programming to "a first set of values suitable for far-field electrogram sensing while the pacing circuit is inactive and programmed to a second set of values suitable for intracardiac electrogram sensing while the pacing circuit is capable of producing pacing pulses," but does not preclude the converse (i.e., the claims do not prohibit utilizing the second values while the pacing circuit is inactive and first values that are suitable for intracardiac electrogram sensing). Levine's modified invention utilizes the first set of values (corresponding to unipolar mode) *both* when the device is inactive (per the "triggered mode," described above) *and* when the device is capable of producing pulses (also per the "triggered mode,"

Art Unit: 3762

described above), and likewise utilizes the second set of values (corresponding to bipolar mode) *both* when the device is inactive (per the “triggered mode,” described above) *and* when the device is capable of producing pulses (also per the “triggered mode,” described above). Since the claim language does not require that the first and second values be *uniquely* applied to the modes wherein the pacing circuit is inactive/capable of producing pulses, respectively, the Examiner maintains the previous grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762